



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0002]

New Animal Drugs; Withdrawal of Approval of New Animal Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) at the sponsor's request because the product is no longer manufactured or marketed.

DATES: The approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5761, [sujaya.dessai@fda.hhs.gov](mailto:sujaya.dessai@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140, has requested that FDA withdraw approval of NADA 093-329 for use of a prolonged-release bolus containing sulfamethazine in cattle because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 093-329, and all supplements and amendments thereto, is hereby withdrawn [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Elsewhere in this issue of the *Federal Register*, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of this application.

Dated: February 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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